Blood Donor Competence, Autonomy, and Relatedness Enhancement

NCT02717338

Informed Consent Form

Child Assent

11/01/18

Ohio University and New York Blood Center Child Assent Form

Title of Research: **Blood Donor CARE**

Researchers: **Christopher France, Ph.D., Janis France, Ph.D., Bruce Carlson, Ph.D., Beth Shaz, M.D., Debra Kessler, M.S., Victoria Frye, Ph.D.**

IRB number: **OU 14-X-256; NYBC 818209**

You are being asked to take part in research. For you to be able to decide if you want to take part, you should understand what the project is about and the possible risks and benefits. This is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks. It also explains how your personal information will be used and protected. Once you have read this form and your questions about the study are answered, you will be asked if you agree to take part. We suggest that you print a copy of this form for yourself.

Summary of Study

This study is designed to help us better understand what leads to a good donation experience and increases willingness to give blood. Recent blood donors will be asked to complete two sets of surveys, several weeks apart, about their blood donation experience and attitudes. Between the two surveys, some donors will complete activities such as a short telephone call, viewing a donor website, and joining a close Facebook group for blood donors. We are interested in learning if these activities affect donor attitudes and behavior.

Explanation of Study

This study is being done to help us better understand what leads to a good donation experience and increases willingness to give blood. It will include 2240 first-time New York Blood Center donors.

The following steps describe what you will be asked to do if you want to participate and how long your participation will last.

1) Begin by reading this form. If you have any questions, email Dr. Janis France at donorcare@ohio.edu.

2) After reading this web page, if you agree to take part in this study please provide your donor ID and your parent/guardian's name and email address at the end of this form. Since you are under the age of 18, your parent or guardian must agree in order for you to participate.

3) After we receive both your assent (this web page) and your parent's consent, we will email you a link to the study web site.

4) When you get the web site link, you can complete the first survey about your thoughts and feelings about blood donation. If you do not complete the survey within a week we will call, email, or text to remind you.

5) After you complete the survey, you will be randomly assigned (like a coin toss) to one of eight groups. You may be asked to have a 10-15 minute phone call, review a blood donor web site for 10-15 minutes, and/or join a closed Facebook group for blood donors. If you agree, the phone call will be recorded for quality control, training, and communication of the research findings.

6) Five weeks after you complete the first survey you will get an email with a link to the follow-up web site. These are the same questions that we asked the first time. We ask them again to see if your thoughts or feelings have changed. If you do not complete the second survey within a week we will email, text, or call to remind you.

7) One year after you complete the second survey we will contact you by phone or email to ask if you donated blood since you took part in the study.

8) Also about one year after you complete the second survey we will use your donor ID code to see if you have donated blood with New York Blood Center since you took part in the study. We will also collect personal data (e.g., date of birth, height, weight, race/ethnicity) and donation details.

Additional information regarding this clinical trial is available from ClinicalTrials.gov using the study identifier (NCT number): NCT02717338.

Risks and Discomforts

There are no anticipated risks to taking part in this study. You will answer questions about you and your thoughts and feelings about blood donation. You may also take part in a phone call, review a web site, and/or join a Facebook group. The study is voluntary. You may stop at any time.

Benefits

This study is important to science and society by helping first-time blood donors decide if they wish to give blood again. You may benefit by getting information to help you meet your own donation goals and intentions.

Confidentiality and Records

Any information from this study that can identify you will be kept confidential. The answers you give will be stored in password-protected files with no personally identifying information. All study data, including recorded phone calls, will be labelled using only a subject code. The master code list with names and contact information will be kept separately in a locked file cabinet in

the research office. The master code list and the phone recordings will be destroyed by January, 2020.

No person will be identified in any publications resulting from this project. You will not be identifiable in any public reports about the study. Information from the study will not be given to anyone except the research staff without your permission unless required by law.

While every effort will be made to keep your study information confidential, there may be instances where this information must be shared with:

* *Federal agencies such as the Office of Human Research Protections, whose responsibility is to protect human subjects in research, or the National Institutes of Health*
* *Representatives of Ohio University (OU), including the Institutional Review Board, a committee that oversees the research at OU.*

Compensation

You will get $100 if you complete the first survey, any assigned task (phone call, web site review, join Facebook group), and the second survey. You will not get paid unless you complete all of your assigned steps. We will need your name and address to mail your check. You will get your check about one month after you complete the second survey.

Future Use Statement

Identifiers might be removed from data/samples collected, and after such removal, the data/samples may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Contact Information

If you have any questions about this study, please contact Dr. Chris France (donorcare@ohio.edu; 740-593-1079) or Dr. Janis France (donorcare@ohio.edu; 740-593-4557).

If you have any questions about your rights as a research participant, please contact Dr. Chris Hayhow (hayhow@ohio.edu; 740-593-0664), Director of Research Compliance, Ohio University.

By providing your donor ID below you agree that:

- *You have read this form (or it has been read to you) and have been given the chance to ask questions and have them answered.*
- *You have been told of potential risks and they have been explained to your satisfaction.*
- *You understand Ohio University has no funds set aside for any injuries*

you might receive as a result of taking part in this study.

- *Your taking part in this research is voluntary.*
- *You may leave the study at any time with no penalty to you. You will not lose any benefits to which you are otherwise entitled.*

*Donor ID:*_____

*Your first and last name:*_____

*Your email address:*_____

*Your parent/guardian's first and last name:*_____

*Your parent/guardian's email address:*_____

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